

and when extracted at reflux temperature for 8 hours with heptane yields total extractives not to exceed 0.1 milligram per square inch of surface.

(e) Polyphenylene sulfide resin coatings containing perfluorocarbon resins complying with § 177.1550 may be used in contact with food at temperatures up to and including normal baking and frying temperatures; provided that the finished cured coating, when extracted at reflux temperatures for 2 hours separately with distilled water, 50 percent ethanol in water, 3 percent acetic acid and heptane, yields total extractives in each extracting solvent not to exceed 0.2 milligram per square inch of surface and when extracted at reflux temperature for 1 hour with diphenyl ether yields total extractives not to exceed 4.5 milligrams per square inch of surface.

[42 FR 14572, Mar. 15, 1977, as amended at 47 FR 11846, Mar. 19, 1982; 54 FR 24898, June 12, 1989]

**§ 177.2510 Polyvinylidene fluoride resins.**

Polyvinylidene fluoride resins may be safely used as articles or components of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, the polyvinylidene fluoride resins consist of basic resins produced by the polymerization of vinylidene fluoride.

(b) The finished food-contact article, when extracted at reflux temperatures for 2 hours with the solvents distilled water, 50 percent (by volume) ethyl alcohol in distilled water, and *n*-heptane, yields total extractives in each extracting solvent not to exceed 0.01 milligram per square inch of food-contact surface tested; and if the finished food-contact article is itself the subject of a regulation in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation. (NOTE: In testing the finished food-contact article, use a separate test sample for each required extracting solvent.)

(c) In accordance with good manufacturing practice, finished food-contact articles containing the polyvinylidene

fluoride resins shall be thoroughly cleansed prior to their first use in contact with food.

**§ 177.2550 Reverse osmosis membranes.**

Substances identified in paragraph (a) of this section may be safely used as reverse osmosis membranes intended for use in processing bulk quantities of liquid food to separate permeate from food concentrate or in purifying water for food manufacturing under the following prescribed conditions:

(a) *Identity.* For the purpose of this section, reverse osmosis membranes may consist of either of the following formulations:

(1) A cross-linked high molecular weight polyamide reaction product of 1,3,5-benzenetricarbonyl trichloride with 1,3-benzenediamine (CAS Reg. No. 83044-99-9) or piperazine (CAS Reg. No. 110-85-0). The membrane is on the food-contact surface, and its maximum weight is 62 milligrams per square decimeter (4 milligrams per square inch) as a thin film composite on a suitable support.

(2) A cross-linked polyetheramine (CAS Reg. No. 101747-84-6), identified as the copolymer of epichlorohydrin, 1,2-ethanediamine and 1,2-dichloroethane, whose surface is the reaction product of this copolymer with 2,4-toluenediisocyanate (CAS Reg. No. of the final polymer is 99811-80-0) for use as the food-contact surface of reverse osmosis membranes used in processing liquid food. The composite membrane is on the food-contact surface and its maximum weight is 4.7 milligrams per square decimeter (0.3 milligrams per square inch) as a thin film composite on a suitable support. The maximum weight of the 2,4-toluenediisocyanate component of the thin film composite is 0.47 milligrams per square decimeter (0.03 milligrams per square inch).

(3) For the purpose of this section, the reverse osmosis membrane consists of a polyamide identified as 2,4-diaminobenzenesulfonic acid, calcium salt (2:1) polymer with 1,3-benzenediamine, 1,3-benzenedicarbonyl dichloride, and 1,4-benzenedicarbonyl dichloride (CAS Reg. No. 39443-76-0). The membrane is the food contact surface and may be applied as a film on a

suitable support. Its maximum weight is 512 milligrams per square decimeter (33 milligrams per square inch).

(4) A cross-linked high molecular weight polyamide reaction product of poly(*N*-vinyl-*N*-methylamine) (CAS Reg. No. 31245-56-4), *N,N*-bis(3-aminopropyl)ethylenediamine (CAS Reg. No. 10563-26-5), 1,3-benzenedicarbonyl dichloride (CAS Reg. No. 99-63-8) and 1,3,5-benzenetricarbonyl trichloride (CAS Reg. No. 4422-95-1). The membrane is the food-contact surface. Its maximum weight is 20 milligrams per square decimeter (1.3 milligrams per square inch) as a thin film composite on a suitable support.

(5) A polyamide reaction product of 1,3,5-benzenetricarbonyl trichloride polymer (CAS Reg. No. 4422-95-1) with piperazine (CAS Reg. No. 110-85-0) and 1,2-diaminoethane (CAS Reg. No. 107-15-3). The membrane is the food-contact layer and may be applied as a film on a suitable support. Its maximum weight is 15 milligrams per square decimeter (1 milligram per square inch).

(b) *Optional adjuvant substances.* The basic polymer identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic polymer. These optional adjuvant substances may include substances permitted for such use by regulations in parts 170 through 186 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) *Supports.* Suitable supports for reverse osmosis membranes are materials permitted for such use by regulations in parts 170 through 186 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(d) *Conditions of use.* (1) Reverse osmosis membranes described in paragraphs (a)(1), (a)(2), (a)(3), and (a)(5) of this section may be used in contact with all types of liquid food at temperatures up to 80 °C (176 °F).

(2) Reverse osmosis membranes described in paragraph (a)(4) of this section may be used in contact with all types of liquid food, except food con-

taining more than 8 percent alcohol, at temperatures up to 80 °C (176 °F).

(3) Reverse osmosis membranes shall be maintained in a sanitary manner in accordance with current good manufacturing practice so as to prevent microbial adulteration of food.

(4) To assure their safe use, reverse osmosis membranes and their supports shall be thoroughly cleaned prior to their first use in accordance with current good manufacturing practice.

[49 FR 49448, Dec. 20, 1984, as amended at 52 FR 29668, Aug. 11, 1987; 53 FR 31835, Aug. 22, 1988; 53 FR 32215, Aug. 24, 1988; 55 FR 8139, Mar. 7, 1990; 59 FR 9925, Mar. 2, 1994]

#### **§ 177.2600 Rubber articles intended for repeated use.**

Rubber articles intended for repeated use may be safely used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The rubber articles are prepared from natural and/or synthetic polymers and adjuvant substances as described in paragraph (c) of this section.

(b) The quantity of any substance employed in the production of rubber articles intended for repeated use shall not exceed the amount reasonably required to accomplish the intended effect in the rubber article and shall not be intended to accomplish any effect in food.

(c) Substances employed in the preparation of rubber articles include the following, subject to any limitations prescribed:

(1) Substances generally recognized as safe for use in food or food packaging.

(2) Substances used in accordance with the provisions of a prior sanction or approval.

(3) Substances that by regulation in parts 170 through 189 of this chapter may be safely used in rubber articles, subject to the provisions of such regulation.

(4) Substances identified in this paragraph (c)(4), provided that any substance that is the subject of a regulation in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

(i) *Elastomers.*